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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/664,958	09/18/2000	Ilya Trakht	60240/JPW/SHS	4881

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Cooper & Dunham LLP  
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EXAMINER

HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 03/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/664,958

Applicant(s)

TRAKHT ET AL.

Examiner

Larry R. Helms

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1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 6,7,9,16-18 and 175-184 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7,9,17 and 18 is/are allowed.
- 6) ☒ Claim(s) 6,16,175-180 and 182-184 is/are rejected.
- 7) ☒ Claim(s) 181 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 111703 . 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Claims 1-5, 8, 10-15 19-174 have been canceled.  
Claims 6, 16, 175-176, 182-183 have been amended.
2. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.
3. The following Office Action contains NEW GROUNDS of rejection.

### ***Rejections Withdrawn***

4. The rejection of claims 6 and 16 and claims 176-184 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.
5. The rejection of claims 6 and 16 and 176-184 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of the amendments to the claims.
6. The rejection of claim 16 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendments to the claim.

***Response to Arguments***

7. The rejection of claims 6, 16 under 35 U.S.C. 103(a) as being unpatentable over De Vries et al (PNAS 95:12340-12345, 1998) and Rousset et al (Oncogene 16:643-654, 1998) and as evidenced by the specification, and further in view of Campbell (Monoclonal antibody technology, Elsevier Science Publishers, pages 1-32, 1986) and Harlow et al (antibodies, A laboratory manual, Cold Spring Harbor Laboratory, page 322, 1988) is maintained.

The response filed 1/12/04 has been carefully considered but is deemed not to be persuasive. The response states that the statement in Campbell does not provide motivation for one skill in the art to raise antibodies to the TIP-2 protein and the statement does not meet the clear and particular standard for motivation (see page 8-9 of response. In response to this argument, the art of both Rousset and De Vries teach antibodies to TIP-2 (see page 12341 of De Vries and page 652 of Rousset) and in view of Campbell it would be obvious to make monoclonal antibodies to TIP-2 and specifically the PDZ region or the C terminus as these were identified as important for interactions with other proteins.

The response further states that in response to the comments about in re Duel, applicants contend that the Examiners logic would lead to the conclusion that the gene coding for the known protein would necessarily be obvious (see page 10). In response to this argument, while the examiner concludes that it would be obvious to clone the gene, it would not be obvious to obtain a specific sequence for the gene, as pointed out in the in re Duel decision, the citation of Dual is concerned with a specific claimed DNA

sequence which is not the case here and does not apply to these claims or its interpretation. In view of the Campbell reference it is obvious to make a monoclonal antibody to TIP-2 and in fact it is obvious to make it to the region that is extracellular.

The response further states that there is no teaching in the prior art of TIP-2 being associated with cancer cells and the references do not teach or suggest all the limitations and the examiner has used impermissible hindsight (see page 10-11 of response). In response to this argument, the claims are to antibodies to TIP-2 and as such the antibodies bind to TIP-2 and would obviously bind to cells that have the antigen on the surface as recited in the claims. Whether or not the prior art identifies the antigen on cancer cells is immaterial because if the antigen is present the antibody would bind and the claims are to the antibody.

The response further states that the examiner has not identified a teaching of TIP-2 antibodies produced by anyone other than applicants and this failure by others makes it unobvious and this is a secondary consideration (see page 11-12 of response). In response to this argument, as stated above both De Vries and Rousset teach antibodies to TIP-2 and therefore the argument is not on target.

8. The rejection of claims 175-180, 182-184 under 35 U.S.C. 103(a) as being unpatentable over De Vries et al (PNAS 95:12340-12345, 1998) and Rousset et al (Oncogene 16:643-654, 1998) and as evidenced by the specification, and further in view of Campbell (Monoclonal antibody technology, Elsevier Science Publishers, pages 1-32, 1986) and Harlow et al (antibodies, A laboratory manual, Cold Spring Harbor

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Laboratory, page 322, 1988) and Adair et al (WO 91/09967, published 7/11/91) and Green et al (Nature genetics 7:13-21, 1994) and Wei et al (U.S. Patent 6,455,040, with priority to 5/99) is maintained.

The response filed 1/12/04 has been carefully considered but is deemed not to be persuasive. The response states that the remarks made in the above rejection be incorporated herein by reference (see page 15 of response). In response to this the same remarks above are directly related to this response.

The response further states that the kits are expressly for detecting the presence of TIP-2 bearing cancer cells and the references do not teach TIP-2 on cancer cells and such detection is indeed an element of the claims. In response to this argument, as stated in the rejection the intended use of the kit carries no patentable weight. It is a well-known convention in the art to place the recited elements in a kit for the advantages of convenience and economy, and methods of detectably labeling antibodies also were well known and available to the ordinarily skilled artisan. Thus, the claimed subject matter is considered obvious over the prior art, absent sufficient factual evidence to the contrary.

***The following is a NEW GROUND of rejection***

***Claim Rejections - 35 USC § 112***

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9. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. claim 16 is indefinite for reciting "binds and forms a complex with TIP-2 located on the surface of fixed human cancer cells expressing TIP-2, wherein the monoclonal antibody binds intracellularly to TIP-2" because it is not clear how the antibody can bind on the surface of fixed cells and also bind intracellularly. Does the antibody bind to the surface or intracellularly?

### ***Conclusion***

10. Claims 7, 9 and 17-18 are in condition for allowance. Claim 181 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (571) 272-0832. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (571) 272-0871.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center telephone number is 703-872-9306.

Respectfully,

Larry R. Helms Ph.D.

571-272-0832



LARRY R. HELMS, PH.D  
PRIMARY EXAMINER